COMMITTEE ON PUBLIC HEALTH RELATIONS

REPORT ON VITAMIN D MILK

The City Department of Health requested the opinion of The New York Academy of Medicine relative to the desirability of making energized milk generally available, and the character of Health Department regulations governing the production and sale of such milk.

A subcommittee was appointed to study the various phases of the problem, and the following is the report prepared by the Subcommittee and adopted by the Committee on Public Health Relations.

Reasons for Vitamin D Milk

It has been satisfactorily demonstrated that in order to prevent rickets, children, particularly during the first year of life, require Vitamin D, in addition to that supplied by the usual foodstuffs. Its administration in terms of fish oils is frequently difficult, although these oils are potent and contain easily available D. Administration by means of irradiated ergosterol and other such substitutes for oil is also at times difficult because of taste and gastric intolerance, and is unsatisfactory because of the lessened availability of the contained D. The inclusion of Vitamin D as an integral part of some palatable food, such as milk, removes these objections and assures ease of administration. Moreover, milk is the universal food for infants; carries with it other vitamins; represents in itself the balanced ration; is rich in calcium and phosphorus; and is an important part of the diet during the period when additional D is most needed.

Methods of Producing Vitamin D Milk

Several processes have been developed for concentrating the active vitamin found in cod liver and similar oils. One of the earliest of these, the Zucker process, is now commercially employed to supply additional D units to food, especially to milk.

The commercial concentrate has 1,500 to 1,800 times the Vitamin D content of the Steenbock standard cod liver oil. After being tested by biological assay at the place of production, it is diluted to a standard strength of 150 D (i.e. 150 times the Steenbock standard cod liver oil, or 195 rat units per gram) and sent to the milk distributor. At the milk plant the material (commercially known as Vitex) is again diluted in a can of milk and then distributed into the large supply vats containing measured quantities of raw milk where it is thoroughly mixed and then sent to the pasteurizers. The dilution ratio, standardized concentrate to milk, is about 1:1,200. The total dilution ratio, full strength concentrate to milk, is about 1:12,000. If desirable the standardized concentrate can likewise be made up in a milk dilution so that the latter figure represents the dilution of added foreign substance. Under the plan of distribution at present adopted, samples of the finished product taken in the market are assayed regularly by a University, State Board, or other equally satisfactory laboratory at the expense of the concentrate manufacturer and under the scientific direction of Dr. Zucker and a faculty committee of Columbia University. At the present time about 100 such assays per month are reported from the various laboratories of which about 60 are from milk supplies.

With continuously increasing market demand for preparations of this sort, greatly enhanced by a large demand for a second grade product used in chicken feed, it has been possible to improve the processes of concentration, to elaborate the procedures of biological control, and, by selection, to improve the quality and the uniformity of the first quality product destined for human consumption.

With the discoveries by Steenbock and by Hess of the influence of ultra violet light of certain wave lengths upon ergosterol, and other organic compounds, a second important source of Vitamin D became available and developments in this field have been extensive and rapid. With regard to milk supplies there have been two particular

outcomes of this work, namely, the feeding of cows with irradiated commercial yeast or ergosterol; and more recently, direct irradiation of the milk itself. The latter process has been extensively investigated as to its clinical, electrical, optical and mechanical details and in particular as to chemical changes in the milk itself. It has been found necessary to limit the time of exposure to a few seconds or to make a corresponding decrease in the intensity of the light in order to avoid unfavorable taste-producing reactions upon the milk fats. The carbon arc lamps produce a high concentration of ozone in their immediate neighborhood and special ventilation provisions have to be made to prevent contact of the milk with this substance which likewise reacts on the fats disadvantageously. The antirachitic potency is imparted to the milk rapidly without appreciably affecting Vitamin A and slightly Vitamin C.

Each of these systems of treatment has its specific mechanical and economic advantages. For the small dealer the avoidance of expensive equipment and the ability to mix up from day to day the exact daily requirements of treated milk are controlling items. To the large distributor, there is claimed at the present time for the process of irradiation an actual overall economy despite a rather heavy initial outlay. The situation has not however been sufficiently developed to justify any direct comparison of costs at the present introductory stage.

The concentrate method enjoys the undoubted advantage of flexibility in that dosages of any required quantity can readily be introduced so that milks could, if desired, be put on the market with differing concentrations for specific purposes. The mechanical operations of the two processes at the plant are perhaps about on a par although the actual operations of homogenizing and mixing are quite familiar to milk plant operators. Here again however it is only fair to await developments and satisfactory evidence that proper control mechanisms have been produced.

Physical, Biological and Clinical Tests

There has been some uncertainty and there are certain conflicting opinions upon the question of the rat unit as a criterion of rickets prevention efficiency in the human infant and the facts in this matter must be established before there can be any satisfactory therapeutic use of Vitamin D preparations of various types. This difficulty, however, is a general one not specific to the milk problem and, in view of the flexibility of the concentrate method at least, offers no insuperable difficulty since any specified dosages are readily obtainable. Under the irradiation procedure as now managed it does not seem to be feasible to obtain a much greater concentration than between 50 to 60 rat units per quart.

From the point of view of sanitary production and of administrative details the two systems are about on a par. The concentrate itself is an anhydrous oil which appears to be bacteriologically sterile as would be anticipated from the method of its production. Being added to the raw milk before pasteurization it introduces no serious sanitary problem. The irradiation procedure likewise is from this point of view similar to other milk handling procedures and is likewise safeguarded by subsequent pasteurization. The somewhat technical point, the addition of a foreign substance to the milk, can be practically avoided, if necessary, by diluting the concentrate in pure milk fat or as is now being experimentally tested, by the use of an evaporated milk as a diluent. Any fortification of natural milk with Vitamin D obviously involves certain additions and chemical alterations in the milk and any milk so modified should be properly labelled to comply with basic pure food laws. If such fortified milks are desirable and are to be approved by the board of health, it is rather quibbling to raise the point of an added foreign substance against either of these two processes.

In the milk of yeast-fed cows there may be considerable variation in the number of rat units per quart, which is due to the difference in the amount of irradiated yeast fed

daily. The potency of the milk depends almost entirely upon the amount of irradiated yeast given and one can conclude that if there is any great variation in the potency of milk of cows fed in this manner, there has been some error in the amount of yeast given to the cows.

As important as the content is the degree of utilization of the Vitamin D. By clinical test this is found to be protective in fortified milk when 24 ounces containing 40 units, are given daily. On the other hand, Kramer and Gettleman believe that unit for unit, there is no difference in the action of directly irradiated milk or milk from cows fed irradiated yeast.

Furthermore, Hess and Lewis (*J.A.M.A.*, July 15, 1933) clinically appraised medicinal oils containing 40 units per gram—"3D"—and found the prophylactic base to be 250 units of cod liver oil D. This work seems to indicate that the availability of D in irradiated milk is five times that of the D content in medicinal oil.

One of the most interesting problems in the therapeutics of rickets is the discrepancy between the rat unit content and the clinical efficacy of various anti-rachitic agents. For example, according to Hess and Lewis, 42 rat units (Steenbock) in the form of irradiated milk, bring about a rapid cure of infantile rickets, whereas 80 units of milk from yeast-fed cows, approximately 160 to 240 units of cod liver oil, and 600 to 800 units in the form of viosterol, are necessary to accomplish a similar result. The ratio of effectiveness of irradiated milk, yeast milk, cod liver oil and viosterol, is therefore, from the point of view of rat units, approximately 15 :8 :4 :1. As a result of these experiences it is impossible to predict the clinical potency of a new anti-rachitic agent merely from its rat unitage. The dosage of new agents can be accurately determined only by experiences in the clinic.

On the basis of the already rather extensive evidence it is safe to assert that Vitamin D milks, irrespective of the manner in which they are produced, are capable not only of preventing but also of curing rickets. If all artificially

fed infants were given Vitamin D milk, rickets would become a rare disorder. It should be noted, however, that occasionally infants will develop rickets in spite of receiving a liberal supply of Vitamin D. These cases are often resistant to treatment with even excessively large amounts of Vitamin D, and should they be encountered in infants receiving Vitamin D milk, it should *not* be deduced from such an experience that the fortified milk has proven to be a failure.

There are at present four designations for units and three different strengths and there is need of uniformity in gauging the curative and preventive potency of the Vitamin D milk for clinical use as well as for health administration purposes.

The assay of the D content of such fortified milks has been time-consuming and expensive. When stated in terms of rat units, the D value must be translated into clinical units and the values of the various forms of D carrying material can not be considered as interchangeable.

Biological assay of energized milk consumes three weeks and provides information too late for practical value.

The most critical detail, however, is the control of the character and intensity of the illumination to secure a uniform and predetermined concentration of the vitamin in the milk. Some very excellent apparatus has been developed for measuring and recording the energy output of the radiating lamp in a certain limited range of the spectrum. It may safely be assumed that these instruments will produce accurate records. The following further assumptions are necessary, however, to justify the acceptance by the administrative officials of any such record as a criterion of Vitamin D productions:

(a) The effectiveness of the various wave lengths of ultra violet light in their ability to produce Vitamin D is paralleled by their respective powers to excite the photoelectric response in the measuring apparatus.

(b) The formation of Vitamin D in milk is a function only of the incident radiation and not of such other physical conditions as temperatures of the milk, chemical composition, etc.

(c) The mechanical details of the operation which determine the time of exposure of the milk to the rays, the thickness of the exposed film, etc., have been so perfected that these important factors may be safely considered to be held constant.

Item (a) has been established by controlled experiment with a reasonable degree of approximation for the limited conditions of the tests. The other items have received only secondary mention.

This indirect test may be capable of complete and satisfactory standardization and would, if so standardized, be of the greatest assistance in the administrative control of the product of Vitamin D milk. Its acceptance for this purpose however must await the most thoroughgoing study of its true significance and during this introductory stage any new installation should be subjected to an extensive over-all calibration of the physical measuring device against the actual anti-rachitic potency of the milk.

Vitamin D Milk for General Consumption

In regard to the question of the possibility of toxic effects resulting from Vitamin D milk, it may be of interest that no one has ever observed any untoward symptoms or hypercalcemia resulting from its administration. It seems that the low titre of rat units in energized milk would preclude such a possibility. Furthermore, feeding rats 10,000 times a therapeutic dose of Vitamin D milk for a period of months did not bring about any deleterious effects, or any abnormal histological changes in the tissues. On the other hand, the need of additional D for well adults is not satisfactorily proven. There is evidence indicating the advantage of additional D in conditions associated with low calcium, in dental caries, during parturition and lactation, perhaps in chronic bone disease and possibly in tuberculosis.

The advisability, therefore, of universal or general energizing of milk does not seem apparent.

Administrative Problem

Assuming that the need for Vitamin D milk has been established, the question then arises as to the responsibility, if any, of official governmental agencies for the regulation and control of the production, handling and sale. This is a question which the committee has considered only because it has been advised that the health departments of the state and the city of New York would welcome an expression of its views.

Apparently neither the State Public Health Council nor the New York City Board of Health has yet undertaken to establish detailed requirements in their respective codes. The State Sanitary Code contains the brief definition that "The term 'Vitamin D milk' means milk in which the Vitamin D content has been artificially increased" and the general provision that it must be made from milk meeting the applicable requirements of the code for milk sold under grade designation. The committee is informed that the question of the need for additional and more specific requirements has been considered by the State Department of Health and the Public Health Council in the recent past and it has been felt that it would be unwise to establish more specific or detailed requirements while the production of Vitamin D milk is still in an experimental stage and until the various scientific and administrative problems involved are better understood.

The State Department has taken the tentative position that it would neither endorse the product nor interfere with its sale so long as it conformed to the above mentioned general requirements. It has felt that this "neutral" position was justified in view of the apparently well founded claims as to the need among children for the product and inasmuch as the possibility of harm resulting from its sale was very remote, providing the milk used was of safe sanitary quality.

It would seem that the principal immediate administrative problem, from the standpoint of protecting the public, is that of assuring that Vitamin D milk sold actually contains the amount of the vitamin which it is represented to contain. It would seem that the health departments, having jurisdiction in matters relating to the sanitary quality and healthfulness of milk, would be the logical agencies to assume such responsibility, so far as it is practicable. From the above discussion it is apparent that the problem is not a simple one. The question of the relative merits of the three available units of measurement is still not completely settled. There are still differences of opinion as to the effectiveness per "unit"—depending on the unit selected—of the vitamin as added by different processes and pending further clinical experimentation it does not seem desirable as yet to form definite conclusions as to what the minimum acceptable standard amount of the vitamin per quart of milk should be. The laboratory procedures required to determine the amount of the vitamin in a specific quantity of milk are involved and expensive and thus far have been undertaken in only a few laboratories, including those maintained and operated for commercial purposes. In view of the expense involved it would not seem to be feasible, under present conditions, for health departments to attempt to set up and finance independent official laboratory service to carry on this work, especially considering the fact that the sale of Vitamin D milk is still limited and that the product is in a sense proprietary.

Involved in the public health aspects of the matter is the question as to what, if any, hazard is involved in the addition of a foreign substance to milk, as is necessary in one of the recognized procedures for increasing the Vitamin D content. While it may be "splitting hairs," the general feeling seems to be that the indirect addition of Vitamin D to milk through irradiation and through the feeding of irradiated yeast to cattle need not be considered the addition of a foreign substance in the commonly accepted sense but that this can not properly be held to apply to the addition of a definite physical substance, as in the case of the

Zucker cod liver oil concentrate. The committee feels safe in venturing the opinion that, considering the fact that this concentrate when it leaves the manufacturer is practically a sterile product, the fact that the amount added to milk is small and the further fact that the procedure involved in adding the concentrate to the milk by the distributor is one not requiring contact with human hands and offering little opportunity for contamination, the hazard, if any, would be so slight as to be negligible, providing the milk was pasteurized after the addition of the concentrate.

Looking at the matter purely from the standpoint of medicine and health, the committee at the moment is unable to see any valid objection to permitting the addition of Vitamin D to milk by any of the recognized methods, under properly controlled conditions.

In view of the fact that the production of Vitamin D milk is still experimental, that existing methods may be changed or improved and, conceivably, new methods may be evolved; that the relative values of units of measurement and the basis for establishing minimum standards for Vitamin D content are still unsettled; and in view of the limited availability of laboratory service for the purpose of making assays, the committee is inclined to feel that the official health agencies in the State and in the City of New York would be acting wisely if they continued, for the present, to defer the enactment of detailed and specific requirements beyond those necessary to assure that the ultimate product be of a safe sanitary quality.

The committee therefore is of the opinion that Vitamin D milk, produced by any one of the three methods, should be allowed to be sold, the containers to carry a label to the effect that it is Vitamin D milk, indicating also the process used. As to whether or not health regulations should require that the label specify that the milk contains a certain specified minimum number of protective units, say 50 per quart, is a matter with regard to which there is still a considerable amount of difference of opinion.

Theoretically, it would be desirable for the producers to state on each bottle the number of units of Vitamin D present in the milk, but in view of the fact that health departments have no laboratory facilities for assaying milk, it is questionable whether this requirement would be practicable. It might perhaps, for the time being at least, be more desirable that the label merely state the source of Vitamin D in each instance, the health department to decide what it considers a normal protective dose and in its license provisions demand proof from time to time that the milk produced under the license contains the stated dosage.

From the evidence now available, the Committee is of the opinion that such requirement will be satisfactorily fulfilled by

1. Directly irradiated milk containing 56 rat units per quart.

2. Concentrate milk and yeast-fed milk containing 100 rat units per quart.

This report was prepared by a special subcommittee consisting of:

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